REMARKS

Status of the Claims

Claims 58, 59, 63, 64, 115-125 and 141-165 are in the application.

Claims 58, 59, 63, 64, 115-125 and 141-165 are rejected.

Claims 58, 59, 63, 64, and 122-125 have been amended, support for which can be found throughout the specification, see, for example, page 1, lines 3-5.

Upon entry of this amendment, claims 58, 59, 63, 64, 115-125 and 141-165 will be pending.

Rejection under 35 U.S.C §112

Claims 58, 59, 63, 64, 115-125 and 141-165 are rejected under 35 U.S.C §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office alleges that specification only discloses using the claimed pharmaceutical compositions for immunization of individuals against pathogen infection and for gene therapy. Therefore, the Office alleges that the compositions "must therefore be examined as therapeutic compositions." The Office also alleges, "If the only disclosed uses for the claimed invention are not enabled, then the claimed invention cannot be considered enabled." Applicants respectfully disagree.

The pending claims are directed to a composition (claim 58), a method of introducing DNA molecules into cells of an individual (claim 115), and a method of inducing antibodies against an antigen (claim 148). The remaining claims depend on one of these claims and define more specific embodiments of the invention. The specification enables one of skill in the art to be able to make and use the claimed invention as defined by the pending claims. ***None*** of the claims recites "A method of inducing protective or therapeutic immunity" or otherwise indicate such a result is required. And since the present specification and the claims neither requires nor excludes protective or therapeutic immunity or other uses that are known to one of ordinary skill in the art, the claims should be not be found to lack enablement.

In the present application the current claims are directed to compositions, methods of inducing antibodies, and method of introducing DNA into a cell. The fact that the claimed compositions and methods might be used to produce protective or therapeutic immunity is tangential to the enablement requirement of the pending claims. The Office has done that which is prohibited by the courts, requiring that a claim be enabled for a process that is ***not*** claimed, not required, or not excluded by the claims or the specification.

The Office is alleging that because a use of the present invention for which the claims are enabled for is not explicitly disclosed in the specification, then the claims are evaluated as to whether they enable how to make and use the invention based solely on the use disclosed in the specification. There is no requirement that any use, much less all uses be disclosed in the specification.[1] This is clearly incorrect and contrary to the M.P.E.P and the law.

The M.P.E.P in discussing the "Test of Enablement" states

> The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent ***coupled with information known in the art without undue experimentation***.

(M.P.E.P. § 2164.01, emphasis added, citations omitted). It is well accepted precedent that "A patent need not teach, and ***preferably omits***, what is well known in the art." (*Id.*). The courts have consistently agreed with this statement. "The specification need not disclose what is well known in the art" *In re Buchner* 929 F.2d 1367.

> A patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan. ***Thus, a patentee preferably omits from the disclosure any routine technology that is well known at the time of application.***

(*Chiron Corp. v. Genentech Inc.*, 70 USPQ2d 1321 (CAFC 2004), emphasis added). "We have admonished against including in the specification material that is known in the art." (*Atmel Corp. v. Information Storage Devices Inc.* 53 USPQ2d 1225.) "Furthermore, a patent need not

[1] See, M.P.E.P § 2107, *Guidelines for Examination of Applications for Compliance with the Utility Requirement.*

teach, and preferably omits, what is well known in the art." *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*,231 USPQ 81; *Spectra-Physics Inc. v. Coherent Inc.*3 USPQ2d 1737.

The M.P.E.P further states

> If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. § 112 is satisfied. ***For example, it is not necessary to specify the...method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation.***

(M.P.E.P § 2164.01, emphasis added). "If any use is enabled when multiple uses are disclosed the application is enabling for the claimed invention." (*Id.*) One of ordinary skill in the art would clearly know how to use the claimed compositions and methods. Therefore, because one of ordinary skill in the art would know how to use the claimed invention for at least one use the pending claims are enabled.

Enablement of how to use a composition does not need to be based solely on the specification. Rather the knowledge of how to make and use a composition can include the knowledge of one skilled in the art coupled with what is taught in the specification. It is instructive as to what the Courts have said in this regard.

> It is well settled that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art.

(*In re Folkers*, 52 CCPA at 175, 344 F.2d 970). Furthermore, the U.S. Supreme Court has stated, "That which is common and well known is as if it were written out in the patent..." (*Webster Loom Co. v. Higgens et al.*, 105 US 580, 586). Accordingly, it is clear that a claimed composition is enabled if with the knowledge of the skilled artisan and/or with what is described in the specification the skilled artisan can make and use the composition for at least one use. Because the claimed composition is enabled for at least one use the claims are enabled.

It has been acknowledged in previous Office Actions that the specification enables the present invention as defined by the claims, i.e. the specification teaches how to make and use compositions and practice methods for the production of antibodies. Thus, the pending claims are in compliance with 35 U.S.C §112, first paragraph. The present rejection is improper as being directed to limitations not included in the claims.

As discussed in Applicants' previous response to the Office, it is well accepted that the production of antibodies has other uses besides providing active immunity (i.e. protective or therapeutic) in the individual which the DNA is injected into. While, active immunity is one reason for generating antibodies, it is not the only reason one of skill in the art would generate antibodies in an individual.

Passive immunity is different from active immunity, in that the antibodies generated against an antigen can be removed from the host and used for other purposes (i.e. administered to another individual or host). Examples of this are prevalent in the immunological industry, and for example, see Applicants response filed March 5, 2004. Antibodies produced using the claimed composition can also be used as diagnostics or to detect the presence or absence of a specific protein. The present invention can also be used to make hybridomas to produce monoclonal antibodies. Therefore, since the compositions can be used for at least one use, the claims are enabled for one of ordinary skill in the art to make and use the invention.

It is abundantly clear that one of ordinary skill in the art would understand that the pending claims are enabled to produce antibodies in an individual, which the Examiner agrees (see above), and that these antibodies would be useful.

The Office, however, indicates that the claims need to enable the skilled artisan to practice "the full scope of the claimed invention." (Office Action, page 8). In support of the allegation that the claims must enable a protective or therapeutic use the Office points to the use the term "pharmaceutical compositions" because the compositions are "intended to produce a therapeutic effect." Applicants respectfully disagree, but have amended the claims to delete the reference to "pharmaceutical" to eliminate any confusion based upon the Examiner's

interpretation of the term. The claims are enabled for a use of the invention. "If any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention." (M.P.E.P. § 2164.01)."

The Office has failed to provide any reasoning or evidence as to why the pending claims when read correctly (*i.e.* without importing the "absent" limitations) are not enabled. In fact, the Office acknowledges that one skilled in the art would reasonably expect the invention as claimed can be used to induce antibodies against an antigen in an individual. Since the compositions are enabled for at least one use the claims are enabled. Furthermore, an individual that is injected with a DNA molecule and a polynucleotide function enhancer of the present invention would be expected to have an immune response that would result in antibodies being produced against the antigen. One of ordinary skill in the art would know and expect that when one administers a composition as described in the specification antibodies would be produced. Protective immunity or therapeutic immunity is not required for the claims to be enabled. However, making and using the present invention to induce antibodies may have a protective or therapeutic response. Either way, the claims to methods of inducing an antibody response would cover the method. The only requirement for the pending claims to be enabled is that one of skill in the art would know how to make and use the invention to induce antibody production in an individual. Antibody production is clearly enabled by both the specification and by the knowledge of one of ordinary skill in the art. Those having ordinary skill in the art would accept the objective truth of Applicants' assertions in view of totality of the evidence.

Accordingly, since the pending claims do not recite elements requiring protective or therapeutic immunity, and the claims ***are enabled*** to one of ordinary skill in the art to make and use present invention to induce antibodies, the claims satisfy the requirements under 35 U.S.C. § 112, first paragraph. In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112 be withdrawn.

Docket No.: UPAP0002-100
PATENT

Serial Number: 09/359,975
Filed: July 23, 1999

Non-statutory Double Patenting

Various claims have been rejected over the judicially created doctrine of obvious-type double patenting as being unpatentable over various claims in U.S. Patent Nos. 5,981,505, 5,817,637, 5,830,876 and 5,593,972. At this time, no claims have been allowed in the instant application. Applicants shall file terminal disclaimers as appropriate upon identification of allowable subject matter. Applicants invite the Examiner to telephone Applicants' undersigned representative at 215-665-6928 to arrange to have such terminal disclaimers transmitted to the USPTO by facsimile upon such identification of allowable subject matter.

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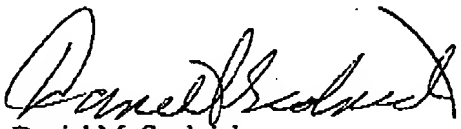
Conclusion

The claims are in allowable form. An indication that the claims are in condition for allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to deposit account no. 50-1275.

Respectfully submitted,



Daniel M. Scolnick

Registration No. 52,201

Date: **January 7, 2004**
COZEN O'CONNOR, P.C.
1900 Market Street
Philadelphia, PA 19103-3508
Telephone: (215) 665-6928
Facsimile: (215) 701-2029